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Quantitative Imaging Workshop XIII:
Lung Cancer, COPD and Cardiovascular Disease
Exploring the Intersections

Rush University Medical Center
IT'S HOW MEDICINE SHOULD BE
AND A SPECIAL THANKS ALSO GOES TO THE

WORKSHOP XIII SPONSOR

Carolyn R. “Bo” Aldigé
Prevent Cancer Foundation

STEERING COMMITTEE

Chair:
James L Mulshine, Rush University

Members:

• Laurie Fenton Ambrose
  Lung Cancer Alliance

• Ricardo S. Avila
  Accumetra, Inc

• Thomas M. Baer
  Stanford Photonics Center/ NPI

• Raul San Jose Estepar
  Brigham and Women’s Hospital

• Elisha Malanga
  COPD Foundation

• David F. Yankelevitz
  Mount Sinai Medical Center
Measuring Progress

Accelerate Development of QI for Screening/Assessment Methods

13 Workshops since 2004
1 Interim COPD Meeting

Interim Meetings

Annual Workshop

Standards & FDA Approval

Reproducibility & Comparison

Publications

Large Open Image Databases

Algorithms & Reference Methods

Open Source Lesion Sizing Toolkit

PCF/Cornell Database
NCIA
Give-A-Scan

Early Clinical Trials
NIST BioChange
Volcano

Quantitative CT Monograph
Annals Translational Medicine Issue

Oncology/ JTO Workshop Reports
ISP Oncology Special Issue
Status of screening implementation

- LDCT lung cancer screening being implemented in US, recommended in Canada and China, not recommended in France
- NELSON trial still awaiting final analysis but...
- Reports on modeling, cohort selection, screening interval, work up refinements
Progress with QI Optimization

QIBA Profile:
Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening

Version 1.0
Date: May 2, 2016
Status: draft

• Document out for public comment
• After reconciliation then work on dissemination
• Aggregate of high quality images to enable regulatory Qualification
• Build on the success of our CDRH 2014-2015 Strategic Priorities. These important areas are critical next steps to reaching our vision:
  – Establish a National Evaluation System for medical devices;
  – Partner with patients
  – Promote a culture of quality and organizational excellence.
In collaboration with U of Nebraska Cancer Center, GE, DOD and NCI, a state-wide pilot CT screening project was designed to screen for lung cancer, COPD and CAD to evaluate feasibility.

Multiple meetings in Omaha and Bethesda to plan the effort.

All collected data was planned to be used as a research resource.
About 438,000 U.S. Deaths Attributable Each Year to Cigarette Smoking*

- Lung cancer: 123,800
- Chronic lung disease: 86,800
- Coronary heart disease: 84,600
- Stroke: 17,400
- Other cancers: 34,700

Cigarette smoking among adults, 18 & older who smoked 30 cigarettes or more a day went down significantly from 2005 -2012 – from 12.6- 7.0%


From 2009-2012 US smoking-attributable economic annual costs were $289-$332.5 billion including $132.5 to 175.9 billion for direct medical care of adults. *(US Surgeon General Report 2014)*
How Do You Approach Integrated LDCT Screening for LCA, COPD, CAD (LCC)?

- From an individual's perspective won't all of this information be overwhelming?
- Won't managing LCC be too expensive?
- If we are scanning for Lung Ca, will that erode the performance of COPD and CAD detection?
- Will saving images of one disease in a clinical/image registry help research related to the other diseases?
- What measures would advance this form of research?
- How to responsibly move from research to public health?
Both conditions are diagnosed with advanced disease related to the presence of symptoms.

Over time, a number of COPD patients develop Lung CA as well as the reverse.

For both, cure is unlikely in late stage disease.

CT is a standard tool for both conditions.

Companion diagnostics are lacking in managing both conditions.

How can we catalyze progress in this area?
Biomarkers as Endpoints in Clinical Trials of Alzheimer’s Disease

Toward an Integrated Academic, Industrial, and Regulatory Perspective

Hampel, Frank, Teipel, Bodke, Hardy, Herholz, Jessen, Broich (BfArM), Katz (FDA Neuropharm), Sanhai (Senior Scientific Advisor, FDA Commissioner), Woodcock (Director, CDER), Zetterberg, Blennow

Biomarker categories:
- target, mechanism, clinical, and diagnostic

Challenges of quality implementation

- Insuring high quality, best practices screening process
- Making sure of compliance with eligibility criteria and CMS registry and shared decision provisions
- Opportunity to enable innovative research in supporting comprehensive data and imaging aggregation registries
Screening As A Health Encounter

• Preventive care for major diseases arising from smoking involves significant opportunities for lifestyle changes to reduce risk

• LDCT be developed as a normative, quantitative health evaluation tool for high risk, asymptomatic, tobacco-exposed populations (tobacco-injury assessment)?

• Annual CT-based tobacco health encounter could bundle coaching on smoking cessation along with other relevant wellness information into an efficient ambulatory prevention encounter focused on addressing major modifiable risk (NCD)

• For success need leading professional associations—cancer, pulmonary, nursing & cardiology to collaborate?
Goal of Workshop

- Identify opportunities or bottlenecks for implementing safe and effective CT based management of early lung cancer and sustaining Continuous Process Improvement
- Ensure the quantitation and methodology are integrated in ways that robust, scalable and economical
- Discuss how to advance thoracic imaging to address the full extent of tobacco injury
- Reframe screening as for tobacco-injury assessment to ensure optimal smoking cessation approaches & for lifestyle changes to reduce risk of premature tobacco-related mortality